St Vincent's Hospital

PARTICIPANT INFORMATION SHEET AND CONSENT FORM

Screening for pancreatic cancer in high risk individuals

CLINICAL RESEARCH

INVITATION

You are invited to take part in a research study that looks at detecting pancreatic cancer before it gives any symptoms.

The study is being conducted by Dr David Williams, Head of Gastroenterology at St Sydney.

Before you decide whether or not you wish to participate in this study, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully and discuss it with others if you wish.

1. 1. **'What is the purpose of this study?'**

The purpose of the study is to see if we can find out if someone has early pancreatic cancer before they show any signs or symptoms of the disease. Detecting pancreatic cancer early could save lives. Currently, routine medical screening and testing for pancreatic cancer is not recommended for people who do not have symptoms or signs of pancreatic cancer.

2. **'Why have I been invited to participate in this study?'**

You are being asked to join this study because you fit into one of the following four groups of people:

- Someone who has been diagnosed by their doctor with Peutz-Jeghers Syndrome,
- Someone who has at least two close relatives known to have pancreatic cancer

- Someone who is a known carrier of a BRCA 2 gene or PALB 2 gene and has a family history of pancreatic cancer
- Someone who has been diagnosed by their doctor with hereditary pancreatitis
- Someone who has been diagnosed with hereditary non-polyposis colorectal cancer (HNPCC) syndrome,
- Someone who has been diagnosed with familial atypical multiple mole melanoma (FAMMM) syndrome.

About 150 people will be asked to join this study over 5 years.

3. **'What if I don't want to take part in the study, or if I want to withdraw later?'**

Participation in this study is voluntary. It is completely up to you whether or not you participate. If you decide not to participate, it will not affect the treatment you receive now or in the future. Whatever your decision, it will not affect your relationship with the staff caring for you.

New information about pancreatic cancer screening may become available during the course of the study. You will be kept informed of any significant new findings that may affect your willingness to continue in the study. If you wish to withdraw from the study once it has started, you can do so at any time without having to give a reason.

You do not have to join this study to be screened for pancreatic cancer. You and your family doctor or specialist, may decide that you have a high risk of getting pancreatic cancer and should have some or all of the same tests done to rule out that you do not have reasons.

4. **'What does this study involve?'**

If you agree to participate in this study, you will be asked to sign the Participant Consent Form. This study will be conducted over 5 years. If everything is normal at the first visit you will be asked to have yearly evaluations. You can withdraw from the study at any time.

Initially, your participation is required for two visits to the hospital during which you will have a consultation, genetic counselling, blood tests and an endoscopic ultrasound (EUS).

We will ask you to make an appointment to come and visit us at We will also ask you to

bring a summary of your medical history from your general practitioner (particularly past history, medications, blood tests measuring your blood count, blood clotting function, kidney and liver function, records of any abdominal surgery, reports from prior computed tomography (CT), magnetic resonance imaging (MRI), or ultrasound of your abdomen for review by our gastroenterologist.

Visit 1: Meet the gastroenterologist and the genetic counsellor

The first time you come to the hospital, you will be seen by one of the study gastroenterologists who will briefly review the study procedures, the risks and the benefits with you and ask you to sign this consent form. You will have your medical history taken and undergo a physical examination. You will also be given a questionnaire to complete. This will take about 15 20 minutes to complete. If you are not able to complete it in the same day we ask you to return it to us by mail at level 4, Department of Gastroenterology, (in the enclosed self-addressed stamped envelope). The questions will ask about your family tree, your use of alcohol or tobacco, perception of risk for pancreatic cancer and other information about your medical history. The information in the questionnaire will allow us to prepare for your next visit.

You will then speak to a family cancer clinician /genetic counsellor, who will review your family history. The counsellor will discuss your risk of developing pancreatic cancer, as well as what is currently known about the genetics of pancreatic cancer. Genetic counselling will be provided to you free of charge, and the counsellor will send you a letter that outlines the information you discussed at this counselling meeting.

Visit 2: During this visit you will have a blood test and an endoscopic ultrasound

You will be asked to come to Endoscopy Department of fasting for 6 hours prior to the test. A needle will be inserted into a vein in your arm (an IV line) to allow us to give you a light anaesthetic for the test and take bloods (aprox 10 ml). The blood will be taken to check for diabetes, inflammation, Ca 19-9 and MIC-1 as part of this study looking for early markers of pancreatic cancer.

Then you will have an endoscopy procedure combined with an ultrasound procedure. The procedure is called EUS (endoscopic ultrasound). An endoscopy is done while you are either sedated or asleep after medications are given through your IV. The procedure

involves passing a flexible tube (the endoscope) down your throat. The tube includes an attached camera and small transducer, which emits sound waves. The tube is passed down into your stomach, as the stomach lies on top of the pancreas. We will use ultrasound waves to take pictures of your pancreas.

During the EUS, we may find that the areas we look at appear to be normal. In this case, the procedure is completed and you will be sent to the recovery room. Once the effects of sedation are gone, you may go home. You need to have someone to escort you home because you had an anaesthetic. We will call you at home in 3 days to see if you had any problems after the EUS. We will ask you some questions about your experience during the screening procedures. A month after the study you will be sent a questionnaire to ask about your experiences during this study. You will then be contacted by the researcher for another follow-up visit to have another endoscopic ultrasound. This visit will be one year after you enrolled in the study.

If the EUS shows an area that looks like a mass or other unusual finding, this may or may not be a sign that cancer is developing. In this case you will receive the best standard of care and will be treated as people with similar problems that are not in the study. For example, if a mass is found during the EUS we may need do a procedure called a Fine Needle Aspiration (FNA). An FNA is a way to collect tissue samples that can be tested for cancer (like a biopsy). The needle is inserted through the endoscopy tube. If a FNA is performed for a cyst, you might be given oral antibiotics for up to 5 days. Sometimes further tests to diagnose your specific problem such as MRI (magnetic resonance imaging) might also be required.

We will call you at home in about three days to see if you had any problems after the test.

Visit 3: Follow up appointment

Once you have finished your tests we will give you an appointment to come back to see your gastroenterologists. He/she will explain the results of all the tests and will give you advice about the follow up. You will have time to ask questions.

If the pathology test results show that you do not have signs of pancreatic cancer we will contact you in a year to see if you wish to return for another endoscopic ultrasound follow- up visit.

If the EUS and FNA results indicate signs of cancer or obstruction of your pancreas or bile duct, the gastroenterologist and an expert pancreatic surgeon will sit down with you and explained the possible options of treatment. You will have time to assess options and decide what treatment you would prefer.

If you would like copies of the actual test results, we can send them to either you and/or your doctor. We can also make recommendations on medical follow-up you might want to consider after the study ends.

5. **'How is this study being paid for?'**

The study is being funded by a grant from St Vincent's Clinic Foundation.

6. **'Are there risks to me in taking part in this study?'**

All medical procedures involve some risk of injury. In addition, there may be risks associated with this study that are presently unknown or unforeseeable. In spite of all reasonable precautions, you might develop medical complications from participating in this study.

Women who are pregnant should not undergo screening EUS procedures that require sedation. If you are pregnant, or think you are pregnant, you will not be allowed to join the study. We will do a pregnancy test if you want to be sure you are not pregnant.

The risks of the procedures are small as EUS is part of standard medical care for certain conditions. Possible side effects of any endoscopic procedure, like the EUS, include soreness of the throat or a reaction to the medications used to put you to sleep. Bleeding, infection, and puncture of your oesophagus, stomach, or intestine are also possible for any endoscopy. The risk of these side effects occurring is about 1 in 1000 patients. If a biopsy (FNA) is performed because an abnormality has been detected the possible side effects include acute pancreatitis, which may occur in 1 to 2 of 100 procedures. This is an inflammation of the pancreas that causes upper abdominal pain, with or without nausea and vomiting. If you develop pancreatitis, you would probably have to stay in the hospital to treat it.

Some patients may develop anxiety or uncertainty related to the abnormal or possibly abnormal EUS screening results. Hence, there is also the risk of anxiety or uncertainty induced by the screening tests and their results. To minimise this, you will receive genetic

counselling and we will tell you the result of the EUS on the day of the test and we will give you a report detailing a summary of the results and future recommendations.

7. **'What happens if I suffer injury or complications as a result of the study?'**

If you suffer any injuries or complications as a result of this study, you should contact the study doctor as soon as possible, who will assist you in arranging appropriate medical treatment.

You may have a right to take legal action to obtain compensation for any injuries or complications resulting from the study. Compensation may be available if your injury or complication is caused by the drugs or procedures, or by the negligence of any of the parties involved in the study. If you receive compensation that includes an amount for medical expenses, you will be required to pay for your medical treatment from the compensation money.

If you are not eligible for compensation for your injury or complication under the law, but are eligible for Medicare, then you can receive any medical treatment required for your injury or complication free of charge as a public patient in any Australian public hospital.

8. '**Will I benefit from the study?'**

This is a screening study, and you may or may not have any medical benefit from having screening procedures. If the screening shows that you have cancer, it will probably be found at an early stage. Treating cancer early in the disease often produces a higher chance of being cured. If you are not diagnosed with cancer, you will not have any medical benefit from being in the study. In the future the information we collect in the study may help to diagnose pancreatic cancer earlier in people at risk for the disease.

9. '**Will taking part in this study cost me anything, and will I be paid?'**

As the study looks only at detection rate of pancreatic lesions participation in this study it will not cost you anything. If you are found to have a lesion you will be treated with current standard of care for patients who have cancer of the pancreas. You will not be paid for joining this study.

10. **What will happen to my tissue sample after it has been used?'**

The blood or tissue sample you provide during the study will be destroyed at the completion of the study.

11. . '**How will my confidentiality be protected?'**

Of the people treating you, only the researcher and the staff involved in your care will know whether or not you are participating in this study. Any identifiable information that is collected about you in connection with this study will remain confidential and will be disclosed only with your permission or except as required by law. Only the researchers will have access to your details and results will be held securely at St Vincent's Hospital .

12. '**What happens with the results?'**

If you give us your permission by signing the consent document, we plan to discuss/publish the results in a medical journal and at conferences. In any publication, information will be provided in such a way that you cannot be identified. We will also share the data as part of this research with other researchers working on pancreatic cancer in other countries. We will not share information that can be used to identify you. Results of the study will be provided to you, if you wish.

13. '**What happens to my treatment when the study is finished?'**

You may be able to continue surveillance following completion of this study if it is found to be of benefit to you. This decision will be made in consultation between you and your treating doctor about the most appropriate treatment for you at that time.

14. '**What should I do if I want to discuss this study further before I decide?'**

When you have read this information, the researcher Dr David Williams will discuss it with you and any queries you may have. If you would like to know more at any stage, please do not hesitate to contact him/her on 02 83822061.

15. **'Who should I contact if I have concerns about the conduct of this study?'**

This study has been approved by St Vincents's HREC. Any person with concerns or complaints about the conduct of this study should contact the Research Office who is nominated to receive complaints from research participants. You should contact them on 02 8382 2075 and quote HREC/10/SVH/33.

Thank you for taking the time to consider this study. If you wish to take part in it, please sign the attached consent form. This information sheet is for you to keep.

St Vincent's Hospital

CONSENT FORM

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1. I,.....of.....
.....agree to participate as a participant in the study described in the Participant Information Sheet attached to this form.

2. I acknowledge that I have read the Participant Information Sheet, which explains why have been selected, the aims of the study and the nature and the possible risks of the investigation, and the information sheet has been explained to me to my satisfaction.

3. Before signing this consent form, I have been given the opportunity of asking any questions relating to any possible physical and mental harm I might suffer as a result of my participation and I have received satisfactory answers.

4. I understand that I can withdraw from the study at any time without prejudice to my relationship to or my medical attendants.

5. I agree that research data gathered from the results of the study may be published, provided that I cannot be identified.

6. I agree that research data gathered from the results of the study may also be shared with other researchers working on pancreatic cancer in other countries. This data will have my identifying information removed and will be stored on secure databases where only approved researchers can access the information.

7. I understand that if I have any questions relating to my participation in this research, I

may contact Dr David Williams on telephone 02 83822061, who will be happy to answer them.

8.I acknowledge receipt of a copy of this Consent Form and the Participant Information Sheet.

9 . We would like to ask you if you would be interested in being contacted for possible future studies related to screening and surveillance for pancreatic cancer, please indicate your preference to be contacted or not on the consent page of this document _

___ Yes, I am willing to be contacted ____ No, I am not willing to be contacted.

Complaints may be directed to the, Research Office, phone number 02-83822075

Signature of participant Please PRINT name Date

_____

Signature of witness Please PRINT name Date

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Signature of investigator Please PRINT name Date

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REVOCATION OF CONSENT

I hereby wish to WITHDRAW my consent to participate in the study described above and understand that such withdrawal WILL NOT jeopardise any treatment or my relationship with or my medical attendants.

Signature Date Please PRINT Name

The section for Revocation of Consent should be forwarded to Dr David Williams, level 4 . Department of Gastroenterology, St Vincent's Hospital, Darlinghurst, 2010.